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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,786	12/28/2001	Shuko Okui	217728US0CONT	3074

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[REDACTED] EXAMINER

HABTE, KAH SAY

ART UNIT	PAPER NUMBER
1624	6

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/028,786	OKUI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>

Kahsay Habte, Ph. D.      1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

1. Claims 1-20 are pending.

### ***Restriction/Election***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part), 2, 3-4 (in part), 5 and 6-20 (in part), drawn to compounds where **A** in formula (1) is pyrazinyl (A-1), classified in class 544, subclass 405.
- II. Claims 1 (in part), 3-4 (in part) and 6-20 (in part), drawn to compounds where **A** in formula (1) is pyrimidinyl (A-2), classified in class 544, subclass 333.
- III. Claims 1 (in part), 3-4 (in part) and 6-20 (in part), drawn to compounds where **A** in formula (1) is pyridazinyl (A-3), classified in class 544, subclass 238.
- IV. Claims 1 (in part), 3-4 (in part) and 6-20 (in part), drawn to compounds where **A** in formula (1) is pyridinyl (A-4), classified in class 546, subclasses 256 and 275.4.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of **A** in formula (1) do not belong to the same recognized class of chemical compounds in the art, and references anticipating one

invention, would not render obvious the others. Group I is drawn to pyrazines (6-membered ring with 2 nitrogens at 1,4-positions) and is different from Groups II-IV, since this is not present in Groups II-IV. Group II is drawn to pyrimidines (6-membered ring with 2 nitrogens at 1,3-positions) and is different from Group I or Groups III-IV. Group III is also different from Groups I-II or Group IV, since it is drawn to pyridazines (6-membered ring with 2 nitrogens at 1,2-positions). Group IV is different from Groups I-III, since it is drawn to pyridines (6-membered ring with a nitrogen) that is not present in other groups. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Harris Pitlick on September 2, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. In claim 1 and elsewhere in the claims, the phrase "general formula" is indefinite. A formula cannot be "general" but specific. For example, Formula (I), Formula (a), Formula (1), etc. are acceptable. It is recommended that applicants delete "general" from said phrase to overcome the rejection.
- b. In claim 1 (line 13), the term "acyl" is indefinite. Does this embrace acids of S? P? As? What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R?
- c. In claims 1, 8 and 16-17, the chemical structures are identified as ".... (1)", "..... (2)", "... (3)" or "... (4)", but it is unclear what the dotted lines represent. It is recommended that applicants delete said dotted lines.
- d. In claims 6 and 7, the composition has no carrier.

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e. In claims 8-20, the phrases "formula (1)", "formula (2)", "formula (3)" (Claim 18), "Y", "Y-1", "Y-2", and "R5", are indefinite. What do said phrases and terms represent? Since claims 8-20 are independent claims, applicants have to recite all the limitation of said formula in claims 8-20. Note that claims 8-18 do not depend on claim 1.

f. In claims 16 and 17, there is no period after the chemical structure.

***Objection***

4. Claim 6 duplicates claim 7. Claim 6 and claim 7 are all drawn to the same compositions. Note that e.g. a pill is the same pill regardless of whom it will be given to.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
September 3, 2003